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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,478	08/14/2001	Morton M. Mower	2206-006 C	1166

7590 08/07/2003
Roberts Abokhair & Mardula, LLC
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EXAMINER

GETZOW, SCOTT M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant(s)	MOWER, MORTON M. on	
	Application No.	09/929,478	
	Examiner	Art Unit	
	Scott M. Getzow	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,15,30,32-34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,15,30,32-34 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1,2,4,15,30,32-34,36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haluska et al '006.

Haluska teaches a device which provides cardioversion in a continuum, from low energy pulses to higher energy pulses to ultimately defibrillation. As shown in figure 2b of Haluska, the level of tachycardia is a function of the heart rate in beats per minute. Thus, the higher the heart rate, or the more severe the tachycardia, the more aggressive the therapy delivered to the patient should be. See also column 12, lines 17-30 where the different therapies are described, and where it is stated that 'Therapies A, B, and C could equally well be defined as cardioverting shocks'. The intensity levels of the biphasic pulses, called for in the independent claims, are considered to be obvious over that described in the Haluska patent, since all possible levels are claimed and the device of Haluska can be adjusted by increasing or decreasing the intensity of the stimulation as desired. See also column 21, line 50 to column 22 line 6, where it is stated that various phases can be used for the stimulation applied to the heart. The use of biphasic stimulation is quite common in the art due to its ability to efficiently stimulate tissue with a minimum energy loss. Regarding claim 30, such a delay

period is considered to be standard in the art in order to avoid pacer mediated tachycardia, or further aggravating the tachycardia, as well as avoiding stimulation during a vulnerable period of the heart beat. Still further, to increase the level of stimulation until 'capture' is realized is standard in the art. Capture or reversion of the tachycardia, once sensed, indicates to the ICD that no more pulses need be applied, while if capture is not achieved then increasing the energy delivered, either through a higher amplitude, pulse width, etc. is indicated.

To make the first phase of the biphasic waveform taught in Haluska *positive* is considered to be common knowledge in the art at the time of applicant's invention.

3. Claims 1,2,4,15,30,32-34,36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilli '229.

Gilli teaches an apparatus which can deliver cardioverting pulses to the heart of a patient. As one of ordinary skill would know, cardioverting pulses have a similar energy level to that of regular pacing pulses, but are simply applied in such a way (e.g. rapid succession of pulses) that they cause the heart to revert from an arrhythmic state to one of normal sinus rhythm. Further, Gilli teaches, at column 15 lines 65+, that '...shock waveforms may be monophasic, biphasic, multiphasic...'. Thus, the cardioverting pulses that are emitted by the Gilli device can be biphasic pulses. Still further, as is clear from the description of the functioning of the Gilli device, (column 5, lines 29+) an automatic procedure is

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performed to determine if capture has taken place. The term 'capture' in the context of the Gilli patent means the reversion of an arrhythmia, such as tachycardia, to a regular heart beat. Also, increasing the energy level, or intensity, of the stimulating pulses in cases where capture did not occur during a first attempt to capture the heart is quite common in the art. In fact, a number of ways of insuring capture are known in the art, including changing the pulse amplitude, modifying the electrode arrangement in order to stimulate another portion of the heart, or applying different waveforms with varying shapes and tilt.

To make the first phase of the biphasic waveform taught by Gilli *positive* is considered to be common knowledge in the art at the time of applicant's invention.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

The remarks made by applicant have been considered, however the above rejections are still deemed to be proper. The patent to Kroll et al (5,534,015) clearly shows biphasic pulses that are used in an implantable heart stimulator, where the first phase is positive. This shows that the limitation added requiring a first phase to be positive was known in the art at least as early as October 11, 1994, the filing date of Kroll et al. It is the examiner's contention that one of ordinary skill in the art would be aware of a wide variety of waveforms suitable for heart stimulation and would consider biphasic waveforms with a positive first phase to be well known in the art, at the time of applicant's invention.

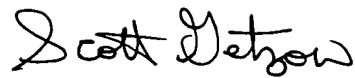
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (703) 308-2997. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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A handwritten signature in black ink, appearing to read "Scott Getzow". The signature is fluid and cursive, with the first name "Scott" and last name "Getzow" clearly distinguishable.

Scott M. Getzow
Primary Examiner
Art Unit 3762

smg
July 28, 2003